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| 10/797,481 | 03/10/2004 | John G. Stark | 5035.01US02 | 3292 |
| 62274 | 7590 | 08/19/2008 | EXAMINER | |
| DARDI & ASSOCIATES, PLLC | | | COMSTOCK, DAVID C | |
| 220 S. 6TH ST. | | | | |
| SUITE 2000, U.S. BANK PLAZA | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/797,481 | STARK, JOHN G. |
| | Examiner | Art Unit |
| | DAVID COMSTOCK | 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 October 2007 and 26 November 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 21-24 and 28-36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 21-24 and 28-36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 13 January 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 October 2007 has been entered.

Claim Objections

Claims 21-24 and 28-36 are objected to because "the" (immediately preceding "opening") should be changed to --an--, since a sacroiliac joint comprises an opening, but a specific location (i.e. "the opening") within the joint has not been set forth.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-24 and 28-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant cites "page 1, lines 27-31" of the specification as "literal" support for the amendment (see Applicant's Remarks, page 6, first paragraph). However, the cited passage does not provide support for inserting an immobilization/fusion element into an opening of the sacroiliac joint along the crack of the joint or extra-articular recess..." as now claimed, but rather provides support for positioning a cutting guide to align a cutting element within the sacroiliac joint, etc. An immobilization/fusion element is neither a cutting guide nor a cutting element. Therefore, it is not seen how this passage provides support for the new claim language. Moreover, it is noted that there is no "darkened area" in Figure 3, as asserted by Applicant, aside from a simple line indicating the shape of the bone (see Remarks, page 7, lines 20-23). All Figure 3 appears to show is a bone screw passing *into* a sacrum. The specification merely says that Fig. 3 shows a sacroiliac joint immobilized with a screw (see, e.g., Brief Description of the Drawings and page 7, lines 10-11.) The description does not say how the screw immobilizes the joint and it would appear the screw goes through bone to accomplish the immobilization. Accordingly, the claims have been interpreted without giving undue weight to the unsupported new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23, 28, 29, 32, 33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by the Cain (U.S. Patent Number 5,334,205).

Cain discloses a method for immobilizing a patient's sacroiliac joint comprising inserting an immobilization/fusion element into the opening of the sacroiliac joint between the ilium, 56, and the sacrum, 54, through a cannula, e.g. 68, that is placed through an incision formed in the patient, drilling a region at the sacroiliac joint through the cannula, and placing a guide pin, e.g. 70, through the cannula, further including a trocar, e.g. 66, self-tapping screws, e.g. 58, and a drilling guide (see figures 3-5 and column 4, lines 4-48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Chang et al. (U.S. Patent Publication Number 20020099288)

Cain discloses the claimed method except for the use of real time imaging. Chang et al. discloses the use of real time imaging in order to guide the placement and orientation of an object (see paragraph 0013 and paragraph 0032). It would have been obvious to one skilled in the art at the time the invention was made to incorporate in the method of Cain the use of imaging in view of Chang et al., in order to guide the placement and orientation of the pin.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Bowman et al. (U.S. Patent Number 4,950,270).

Cain discloses the claimed invention except for the screw being associated with or coated with a biologically active agent. Bowman discloses a screw and teaches that the screw is constructed and/or coated with a biocompatible material and teaches the use of biocompatible material to allow for permanent or long term placement in association with cancellous bone and soft tissues and to promote osteointegration (see Column 3, lines 13-17). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cain with the screw being associated with or coated with a biologically active agent in view of Bowman, in order to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Helland (4,488,542).

Cain discloses the claimed invention except for the immobilization/fusion element being an unthreaded pin. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the immobilization/fusion element without any threads, for example, to reduce cost or facilitate placement of the element in bone, since applicant has not disclosed that doing so solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an immobilization/fusion element for the joint. *In re Dailey and Eilers*, 149 USPQ 47 (1966). Moreover, bone pins and bone screws are very well-known functional equivalents in the art for providing fixation of bone, and either could be used by a person having ordinary skill in the art (e.g., an orthopedic surgeon) as desired and/or to accommodate individual patient conditions. For example, Helland teaches that internal bone fractures may be fastened by means such as screws, nails, pins, etc. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted a pin for a screw as the immobilization/fusion element, as desired and/or to best accommodate individual patient conditions, in view of Helland, as such would amount to nothing more than the substitution of functionally equivalent structures that are known in the art for treating bone.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Skiba (5,743,914).

Cain discloses the claimed method except for explicitly reciting that the immobilization/fusion element could have a central channel and be inserted over a guide pin. Again, although such a well-known and obvious feature should not even require any belaboring, it is noted that Skiba (for one example) shows a bone screw and teaches that it may be provided with a central channel and be inserted over a guide pin to "ensure optimal placement of the screw and, thus, proper mending of the bone structure." (col. 6, lines 39-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to likewise have provided the immobilization/fusion element of Cain with a central channel and to have inserted it over a guide pin, in view of the knowledge generally available to a person having ordinary skill in the art and numerous prior art references, including Skiba, in order to, for example, ensure optimal placement of the screw and proper mending of the bone structure.

Response to Arguments

Applicant's arguments filed 17 October 2007 have been fully considered, but they are not persuasive.

The immobilization/fusion element shown in Cain is inserted into an opening of a sacroiliac joint and is through and necessarily between the ilium and sacrum (for example, as it does not circumvent or in any way go up, over and/or around these bones). Thus, the element is between the ilium and sacrum at least because it is between the bones as by the boundaries of the same. Moreover, (and in response to

Applicant's argument on a technicality that depends on the removed bone material), the element is also literally between the bone material, for example, as viewed along a non-axial (with respect to the element), or angularly offset, frame of reference.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies, for example at page 9, lines 10-14, "initially penetrating and directly accessing the sacroiliac joint," are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's remaining arguments are moot in view of the rejections and remarks already set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733